

Case in Point

Investigation Services for the Pharmaceutical Industry

Whether it is a matter of internal theft, poor quality assurance procedures, or pharmaceutical counterfeiting, Vance can conduct discreet and thorough investigations to reduce the risk of fines, license suspensions, and revenue losses due to theft.

Client

Generic drug manufacturer

Client Profile

One of the world's top five generic drug manufacturers headquartered in Europe with a wide network of international production facilities in various countries. The company has more than 350 medicines available and more than 350 in development.

Business Situation

The manufacturer's distribution center received a shipment of morphine from the manufacturing plant, signed for the shipment, and then noticed that there was a 12x10 box of 30mg morphine capsules missing from the skid. After the supervisor in the manufacturing plant was notified of the missing box, he informed his manager, who notified the company's attorneys, and an internal investigation was launched immediately. The Drug Enforcement Administration (DEA) was also notified, as part of the entities notification policy.

Challenges

Most large drug companies have thorough polices and procedures that dictate the steps employees should rigorously follow to maintain the integrity of the manufacturing process. It would be ideal to be able to say that theft and wrongdoing can be prevented by the judicious and committed application of these policies and procedures, but, unfortunately, the crime is too lucrative. Most employees will be deterred, but there will always be those who believe they can get away with it. According to the DEA, employees of pharmaceutical drug manufacturers and commercial distributors account for most of the drugs or medicines diverted through theft.

The company's own internal investigation attempted to reconcile the paperwork between the shipper and receiver, but ultimately determined that it was not a paperwork mix-up. It was likely theft that involved an employee or an outside criminal in collusion with an employee.

It was at that point that the management team and the company's lawyers became concerned that this type of issue might have happened in the past and/or it could happen again unless they did a thorough risk assessment of their entire manufacturing process. The law firm called Vance because of its reputation for quality investigation in the pharmaceutical industry.

The Vance Solution

- Conducted in-person interviews—with the Vice President of the company, the Vice President for Quality and Compliance, and a select group of employees to assess how procedures were or were not followed.
- Reviewed security technology systems—and determined CCTV systems were analog and outdated. The Vance investigator also determined that there were not enough cameras installed in the plant, and supervisors within the facility did not have visibility into vulnerable areas of the plant. As a result, there were significant security gaps in monitoring the manufacturing process from raw materials and packaging to storage and shipping.
- Reviewed batch records—and determined that the plant was allowing a five percent loss in manufacturing and a three percent loss in packaging. That amount was equal to approximately 30,000 capsules that were unaccounted for.
- Assessed the control of Schedule 2 drugs—and found that boxes of medicines were being moved in and out of the vault without being noted in the log.
- Reviewed DEA reporting procedures—and determined that not all employee social security numbers were being reported to the DEA and that criminal background checks had not been conducted on all employees.
- Reviewed standard operating procedures—related to shipping and receiving and found established procedures were not being followed.



Throughout the investigation, the Vance examiner found numerous weaknesses in the company's procedures, security technology, monitoring capability, and record keeping. As a result of Vance's recommendations to update camera systems using digital technology, install access control, and tighten procedures, the company was able to then assign these tasks to specified individuals with Vance monitoring the progress.

Benefits

- Prevent licenses from being revoked
- Reduce the risk of fines and penalties being levied against the company
- Identify security gaps, particularly in the areas of the packaging and distribution chain
- Increase awareness and perception of the problem at many stakeholder levels
- Improve coordination between distribution centers and manufacturing plants
- Demonstrate good faith to the Food and Drug Administration and DEA that investigating suspicious activity of product loss is taken very seriously

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Contact a Vance Expert:

+1 (703) 592-1400
info@gardaglobal.com

www.vanceglobal.com
www.gardaglobal.com